

REMARKS

Claims 22-30 remain pending in this application.

The amendment to claim 22 is supported in the specification at, for example, page 23, lines 9-17. The specification has been amended to update the priority information. Applicants respectfully request approval and entry of the amendments to the claims and specification.

CLAIM REJECTIONS -- 35 U.S.C. § 112

Claims 22-25 have been rejected under 35 U.S.C. § 112, second paragraph.

Applicants respectfully traverse this rejection. The meaning of claim 22, as originally presented, is clear and unambiguous. Nonetheless, in order to advance prosecution and clarify the claims further, claim 22 has been amended to delete the words "up to." As mentioned above, this amendment is supported at, for example, page 23, lines 9-17 of the specification. Applicants respectfully submit that claim 23, as originally presented, is also clear and unambiguous. The explicit recitation of inherent features is not necessary for compliance with the second paragraph of Section 112. Nonetheless, in order to advance prosecution and clarify the claims further, claim 23 has been amended above to address the Examiner's concerns.

For these reasons, Applicants respectfully submit that all active claims are in full compliance with Section 112, and request reconsideration and withdrawal of the Section 112 rejection.

CLAIM REJECTIONS -- 35 U.S.C. § 103

Claims 22-30 have been rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 3,845,217 to Ferno et al. (hereinafter "Ferno").

The Examiner states that Ferno's chewing gum composition includes each of Applicant's claimed components, and alleges that column 3, line 68 to column 5, line 6 teach that the amount of nicotine can be adjusted to give a quick release or a slow release. The Examiner concludes that finding the optimum nicotine release rate and effective concentration would require no more than routine experimentation by one reasonably skilled in the art.

Applicants respectfully traverse the rejection.

Even though Ferno is concerned with a nicotine-containing chewing gum, and includes ingredients disclosed in the subject application, Ferno's gum differs from the claimed invention. The chewing gum of claim 22 achieves a relatively rapid initial nicotine release rate of at least about 25% within about 5 minutes, followed by a sustained nicotine release rate of at least about 80% within about 30 minutes of chewing. The chewing gum of claim 26 provides an initial nicotine release which achieves a loaded nicotine concentration in a user's blood of between about 2 and 7 nanograms per milliliter of blood within 5 minutes after chewing begins, and maintains the loaded nicotine concentration in the user's blood for an additional about 30 minutes thereafter. The chewing gum of claim 28 achieves a relatively rapid initial nicotine release rate of at least about 25% within about 5 minutes,

followed by a sustained nicotine release rate of at least about 60% within about 30 minutes of chewing.

As discussed during the interview in the parent application, Ferno's gum does not achieve the nicotine release profiles of these claims.

A Rule 132 Declaration, submitted in related application 09/389,339 and resubmitted herewith, corroborates the above-discussed differences between the claimed invention and Ferno. The Declaration sets forth data comparing the nicotine release rate of several inventive chewing gum samples with the rate of nicotine release of Nicorette®, a commercial nicotine-containing chewing gum. It is believed that the Ferno patent is a description of the Nicorette® commercial product. The data shown in the Declaration illustrates the unobviousness of the claimed invention over Ferno.

Referring to paragraph 2 of the Declaration, it can be seen that a 2.0 gram sample of Nicorette® and two 2.0 gram samples of inventive gums were prepared for testing. One inventive sample gum used nicotine polacrilex as the active ingredient while the other used a nicotine salt. The Nicorette® sample used nicotine polacrilex as the active ingredient. The graph attached to the Declaration illustrates the percentage of available nicotine released from the respective samples over a thirty-minute interval during a "chew out" test that was conducted under uniform conditions. The "chew out" test is described at page 29, lines 9-32 of the subject application. The graph shows that within the first five minutes, the

inventive samples released about 25% or greater of the available nicotine while the Nicorette® sample released about 6%.

The 6% nicotine release of Nicorette® does not reasonably suggest the claimed range of at least about 25%. Applicants respectfully submit that the optimization doctrine does not overcome this deficiency. In order for the Examiner to rely on the doctrine of optimization, there must be motivation within the applied art and/or the prior art as a whole to modify the feature to arrive at the claimed invention:

The PTO and the minority appear to argue that it would always be obvious for one of ordinary skill in the art to try varying every parameter of a system in order to optimize the effectiveness of the system even if there is no evidence in the record that the prior art recognized that the particular parameter affected the result. As we have said many times, obvious to try is not the standard of 35 U.S.C. § 103. Disregard for the obviousness of the results of "obvious to try" experiments disregards the "invention as a whole" concept of § 103.

In re Antonie, 195 U.S.P.Q. 6, 8 (C.C.P.A. 1977).

In other words, it is not enough that the cited art provides motivation to solve a particular problem addressed by the inventors; rather, the cited art must teach solving the problem by employing the claimed features or process steps.

Here, Ferno fails to teach both the particular problem addressed by the present inventors and the claimed features employed by the present inventors to solve that problem. Ferno does not discuss the problem of periodic and episodic peaks or surges of nicotine cravings that users encounter. Ferno also fails to teach the importance of rapid release of nicotine over the first few minutes of chewing to relieve cravings that, unless treated, may result in relapse. Given these deficiencies, one of ordinary skill

in the art would not have been motivated to modify the nicotine release profile of Ferno in the manner taught by the present inventors. To state in conclusory fashion that it would have been obvious to try and optimize features, such as the release profile, when the cited art reference admittedly contains no motivation for attempting to do so, simply because the modification can be made, is to misapply the standard for determining obviousness. *In re Eli Lilly & Co.*, 902 F.2d 943, 14 U.S.P.Q.2d 1741 (Fed. Cir. 1990).

For these reasons, Applicants respectfully request reconsideration and withdrawal of the Section 103(a) rejection of claims 22, 26, and 28 based on Ferno. Applicants further respectfully submit that claims 23-25, 27, 29, and 30, being dependent from these claims and including all of the distinguishing features of their respective independent claims, are patentable over the cited art for the above-discussed reasons and for the additional reason that the added subject matter of dependent claims, when viewed as a whole, is neither disclosed in nor reasonably suggested by Ferno.

CLAIM REJECTIONS -- DOUBLE PATENTING

Claims 22-30 have been rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-21 of U.S. Patent 6,344,222 (hereinafter “the ‘222 patent”).

Applicants respectfully traverse the rejection.

Applicants point out that the subject application and the '222 patent do not share common inventorship or ownership. The '222 patent includes inventors Cherukuri and Sasan, who assigned their interests in the patent to Fuisz Technologies Limited via an assignment recorded on April 15, 2002 at Reel/Frame 012796/0569. The present application has been assigned to JSR LLC alone, via an assignment recorded on November 10, 1999 and recorded at Reel/Frame 010370/0292. Accordingly, Applicants respectfully submit that the obviousness-type double patenting rejection is inappropriate, and should be withdrawn.

Claims 22-30 have been rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-27, 36-42 and 57-74 of U.S. Patent 6,358,060 (hereinafter "the '060 patent").

A terminal disclaimer has been filed herewith. Applicants respectfully submit that the double patenting rejection over the '060 patent has been overcome by the terminal disclaimer. Applicants respectfully request withdrawal of the rejection.

CONCLUSION

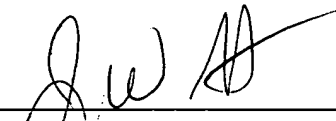
In view of the foregoing, Applicants respectfully submit that the pending claims are allowable and that the application is in condition for allowance.

Reconsideration of the application in view of this Response and its passage to issue are respectfully requested.

If, after reviewing the above, the Examiner believes any issues remain unresolved, the favor of an Examiner interview is requested and the Examiner is requested to contact the undersigned, by telephone, to schedule same.

Respectfully submitted,

LINIAK, BERENATO & WHITE

By: 
Joseph W. Berenato, III.
Registration No. 30,546
Tel. No. (301) 896 0600
Fax. No. (301) 896-0607

May 4, 2004

Liniak, Berenato & White
6550 Rock Spring Drive
Suite 240
Bethesda, MD 20817
(301) 896 0600
(301) 896 0607 (fax)